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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,325	09/02/2003	Allan H. Graff	C75128-1	2971

7590 09/20/2006

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,325	GRAFF ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, amendment and remarks, all filed 6/23/06. Claims 1-32 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/06 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The specification as originally filed does not support "active agent" that is "substantially contained within the glassy matrix." The specification at least at paragraphs [0012], [0020], [0023], [0033], [0034], [0036], [0046], [0069], [0062] and [0074] supports "at least one substantially non-hygroscopic" sugars and not active agent that is substantially contained with the glassy matrix. Paragraph [0041] states that "the nicotine active" is "substantially contained in the glassy matrix" and not a generic active agent.

The rejection may be overcome by reciting nicotine active instead of the broad active agent.

5. Claims 9-11 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 9 recites the limitation "said gum" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not provide support for gum or there is no recitation of gum in claim 1.

7. Claim 18 recites the limitation "the nicotine active" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of nicotine active or active agent that is nicotine.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: while the original claim 6 recites "prior to ingestion," the specification does not provide support for the phrase.

The specification may be amended to incorporate the phrase without raising the issue of new matter.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 1-4, 6-8 and 32 under 35 U.S.C. 102(e) as being anticipated by Ream et al. (US 6,290,985) will not be made in the RCE examination of the claims in view of applicant's persuasive argument that Ream discloses a coated dosage form that is not a lozenges or glassy dosage form.

11. Claims 1-11, 13-16, 22, 26, 27 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Muhammad et al. (US 5,167,964).

Muhammad discloses flavored lozenges formulation and that lozenge bases are generally hard boiled candy lozenges or compressed tablet lozenges (column 8, lines 53-58). The disclosure of lozenges meets the limitation of claim 27. Muhammad specifically discloses that hard-boiled candy lozenges are amorphous or glassy (column 8, lines 59-64) meeting the limitation of claim 1a. Muhammad's formulation comprises medicaments and nicotine is specifically mentioned (column 4, lines 47 and 48) with the nicotine meeting the limitation of

claims 1c and claims 2, 3, 16 and 32. The formulation comprises bulking agents, flavoring agents sweetening agents and buffers (column 8, lines 31-33; column 2, lines 60-65; column 10, lines 64-68); the buffering agents and flavoring agents meet the limitations of claims 22 and 26 and with regards to claim 26, "non-pharmacological component" is a flavor agent according to the instant specification at paragraph [0039]. The formulation may comprise 95% of a mixture sugar alcohols of sorbitol and mannitol in a ratio from about 9.5:0.5 to about 7.5:2.5 (column 9, lines 12-17) meeting the limitations of the claim 1b and the 95% sugar alcohol of Muhammad meets the limitations of claims 13-15. Claims 6-8 recite the properties of the dosage form of claim 1, and since a composition cannot be separated from its properties and because Muhammad discloses the dosage of claim 1, it flows that the dosage form of Muhammad possesses the properties recited in claims 6-8. Sufficient amount is any amount deemed sufficient by the artisan. For example, Muhammad specifically discloses that the effective amount of the medicament may vary depending on the recommended therapeutic dosage or the dose permitted for the particular medicament and that such dosages are known to the skilled artisan in the medical arts (column 5, lines 10-16). Furthermore, the formulation/dosage of Muhammad contains suspending or thickening agents such as carrageenans, xanthan gums, gelatin and celluloses, with the preferred amount of the thickener present at from about 1% to about 15% and a point within this range anticipates the recited amounts of gum in claims 9-11 and the presence of xanthan gum in the dosage of Muhammad meets the limitations of claims 4, 5 and 9-11. The nicotine is contained in the glassy matrix.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The rejection of claims 10-21 under 35 U.S.C. 103(a) as being unpatentable over Ream et al. (US 6,290,985) is not made in the RCE examination in view of applicant's persuasive argument that Ream does not disclose a hard lozenges or glassy dosage form.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964).

Muhammad is discussed above. While Muhammad discloses the use of phosphate buffers (column 2, line 65 and column 10, lines 64-66), there is no disclosure for specific phosphate buffers. But, the phosphate buffers recited in claim 23 are common phosphate

buffers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the known phosphate buffers and expect the formulation to be buffered at the desired pH.

16. The rejection of claims 1-32 under 35 U.S.C. 103(a) as being unpatentable over Ventouras (US 6,183,775 B1) is not made in this RCE prosecution because the lozenges of Ventouras as argued by applicant is not a hard (see Ventouras at column 4, lines 24-26) and thus applicant's argument is persuasive.

17. Claims 12, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad (US 5,167,964) in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Muhammad discloses the dosage of claim 1. Muhammad does not disclose the mixed sugar alcohols of claims 12 and 21. Regarding claim 25, it is noted that the dosage formulation of Muhammad comprises the sugar alcohol recited in claim 25 and the ordinary skilled artisan would know to use amounts of the sugar alcohols desired in the production of the lozenges.

However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1.6-GPS, 1.1-GPS and 1.1-GPM (abstract; column 4, lines 38-67). Also, Burnick discloses formulation that contains nicotine, ISOMALT and xanthan gum (abstract; paragraph [002]; paragraph [0012]; paragraph [0015].

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine lozenge Muhammad. One having ordinary skill in the art would have been motivated to use mixed sugar alcohols known in the art to be formulated

with nicotine according to Rapp or Burnick with the expectation of imparting low hygroscopy to the lozenge. ISOMALT is a mixture or 1,6-GPS and 1,1-GPM.

Response to Arguments

18. Applicant's arguments filed 6/23/06 with respect to Ream have been considered and found persuasive. The rejection is not made in this RCE examination.

19. Applicant's arguments filed 6/23/06 as they relate to Venturas have been fully considered and have been found persuasive as it regards to hard candy-like lozenges.

Rapp and Burnick are relied upon for disclosing nicotine compositions that contain ISOMALT.

20. In response to applicant's arguments against the references individually (Rapp and Burnick), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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